

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

TRANSLATION
PCTWRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

Applicant's or agent's file reference

04P00097WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/017706

International filing date (day/month/year)

29.11.2004

Priority date (day/month/year)

02.12.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

Shionogi & Co., Ltd.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

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Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
- ☐ paid additional fees under protest
- ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

The compounds stated in claim 24 are included in the formula (I) stated in claim 1.

Before the filing date of the present application, compounds having a benzene ring existing at the 3-position of isoxazole through a group represented by $-CR^3R^4-X^1$ and further having $-COOR^{17}$ bound at the end through two atoms were publicly known (for example, see Example 41 of WO, 03-084916, A2). So, it is not considered that the compounds described in claim 1, the compounds described in claim 20 and the compounds described in claim 22 have a novel common basic structure.

In view of the above:

I. The special technical feature of the subject matters of claims 1-19, 24 and 25 and claims 26 and 27 quoting the said claims is the compounds of [Chemical formula 1].

II. The special technical feature of the subject matters of claims 20 and 21 and claims 26 and 27 quoting the said claims is the compounds of [Chemical formula 4].

III. The special technical feature of the subject matters of claims 22 and 23 and claims 26 and 27 quoting the said claims is the compounds of [Chemical formula 5].

In view of the above, since there is no technical relationship among the inventions I-III involving one or more of the same or corresponding special technical features, these inventions are not considered to be so linked as to form a single general inventive concept.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos. _____

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-27	YES
	Claims		NO
Inventive step (IS)	Claims	3, 14, 20-23, 25	YES
	Claims	1, 2, 4-13, 15-19, 24, 26, 27	NO
Industrial applicability (IA)	Claims	1-27	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: WO, 99-11255, A1 Document 2: WO, 01-36365, A2 Document 3: WO, 02-092550, A1</p>			
<p>I. Claims 1-19 and 24-27</p> <p>(i) Claims 1, 2, 4-13, 15-19, 24, 26 and 27 The subject matters of claims 1, 2, 4-13, 15-19, 24, 26 and 27 do not appear to involve an inventive step in view of documents 1-3.</p> <p>Document 1 describes the compounds represented by the general formula (I) and having peroxisome proliferator activated receptor (PPAR) agonist activity, and Examples 26-192 describe compounds having a chemical structure similar to that of the compounds of the present application. Since it is often practiced to change substituent groups for obtaining compounds most suitable or normally suitable as drugs, a person skilled in the art could have easily conceived of the compounds of the present application by changing the combination of substituent groups in the said general formula (I).</p> <p>Document 2 (Example 117) and document 3 (Example 16) describe compounds having a chemical structure similar to that of the compounds of the present application. Furthermore, documents 2 and 3 also describe that the said compounds are useful for therapy of psoriasis, eczema, atopic dermatitis, etc. These diseases are included in the diseases capable of being cured by the PPAR agonist drugs of the present application (see paragraph [0132] in the specification of the present application). Since it is often practiced to change substituent groups for obtaining compounds most suitable or normally suitable as drugs, a person skilled in the art could have easily variously changed the substituent groups of the compounds described in documents 2 and 3.</p> <p>(ii) Claims 3, 14 and 25 The subject matters of claims 3, 14 and 25 appear to be novel and to involve an inventive step in view of documents 1-3.</p> <p>None of documents 1-3 describes or suggests that a substituent group other than hydrogen is used for substitution at the 4-position of isoxazole. Furthermore, the compounds of the present application exhibit an especially remarkable effect that PPAR transcription activity can be greatly improved if a substituent group other than hydrogen is used for substitution at the 4-position of isoxazole (paragraph [0327] in the specification of the present application), compared with the compounds not yet substituted.</p>			

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Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

II. Claims 20 and 21

The subject matters of claims 20 and 21 appear to be novel and to involve an inventive step in view of documents 1-3.

None of documents 1-3 describes or suggests the compounds described in claim 20 of the present application, and it is not considered to be obvious for a person skilled in the art to conceive of the said compounds.

III. Claims 22 and 23

The subject matters of claims 22 and 23 appear to be novel and to involve an inventive step in view of documents 1-3.

None of documents 1-3 describes or suggests the compounds described in claim 22 of the present application, and it is not considered to be obvious for a person skilled in the art to conceive of the said compounds.

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Box No. VI

Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
US 2004/0209936 A1 [EX]	21.10.2004	06.02.2004	17.04.2003

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

International Patent Classification (IPC)

Int. Cl⁷ A61P37/08, 1/04, 19/02, 1/18, 17/06, 17/04, 19/10, 15/00, 35/00, 25/28, 25/16